REMARKS

Status of the Claims

The present Office Action addresses and rejects claims 7-28 and 41-44. Applicant respectfully requests reconsideration in view of the remarks herein.

Rejections Pursuant to 35 U.S.C. § 112

Claims 7-10, 42, and 43 are rejected pursuant to 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner argues on page 2 of the Office Action that "the specification does not describe at least one through hole of a first biocompatible pledget 'having a minimum diameter greater than a maximum diameter of the suture'" as recited in independent claim 7. Applicant respectfully disagrees.

Paragraph [0036] of the published application clearly describes that "[w]hen the device 10 is deployed, the tissue to be fixed can be positioned between the first pledget 24 and the securing elements 14, 16 with strands of the suture 12 passing through holes in the tissue." Moreover, FIGS. 1-4 specifically illustrate that the holes (32) of the first pledget (24) have a minimum diameter greater than a maximum diameter of the suture (12) at least because the suture (12) passes through the holes (32) and is threaded through each of the holes (32) twice, thereby providing clear support for this limitation in claim 7.

Applicant further notes that 35 U.S.C. §112, first paragraph, states that the specification "shall contain a written description of the invention . . . to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same" and that the "subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP § 2163.02. The specification of the present application clearly and precisely contains a written description of the invention that is more than sufficient to enable a person skilled in the art to make and use a tissue fixation device including a suture and a first bioimplantable pledget having at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture. Reconsideration and withdrawal of this rejection is therefore respectfully requested.

Claims 8-10, 42, and 43 were apparently rejected only because of their dependency on claim 7. Because claim 7 complies with the written description requirement as discussed above, claims 8-10, 42, and 43 also comply with the written description requirement.

Rejections Pursuant to 35 U.S.C. § 103

Richards

Claims 11-13, 15, and 22-26 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,669,473 ("Richards"). Applicant respectfully disagrees.

Independent claim 11 recites a tissue fixation device including a suture suitable for in vivo placement in a human or animal body, a first biocompatible securing element connected to a first portion of the suture, and a second biocompatible securing element connected to a second portion of the suture. Each of the first and second securing elements are rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in human or animal tissue to a second position substantially perpendicular to the first position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in the human or animal tissue. The tissue fixation device also includes a deployment instrument having first and second tubes configured to deliver the first and second securing elements in the first position through the tubes and through the respective hole formed in said tissue.

The Examiner argues that Richards discloses the claimed invention except that

> Richards et al. do not specifically disclose that the second biocompatible securing element is rotatable from a first position to a second position substantially perpendicular to the first position when the tissue fixation device is deployed. Nevertheless, Richards et al. teach, at least in col. 4, line 55 to col. 5, line 6 and col. 5, lines 43-49; that a securing element not only tends to rotate from a first position to a second position substantially perpendicular to the first position, the securing element, when tugged upon during deployment in tissue, 'tends to set the fastener even deeper into the tissue' (i.e., the securing element, when deployed in tissue, is able to be rotated beyond the nearly-perpendicular angle shown

> in the figures). In other words, the securing element is indeed rotatable or capable of rotating from first position to second position substantially perpendicular to the first position, when the device is deployed in tissue.

Office Action, p. 3-4.

Richards Specifically Discloses That Its Fastener Heads Do Not Rotate To A Substantially Perpendicular Position When Deployed

The Examiner is misrepresenting Richards. Richards does not disclose that "the second biocompatible securing element is rotatable from a first position to a second position substantially perpendicular to the first position when the tissue fixation device is deployed" because Richards discloses the *exact opposite*. As previously pointed out by Applicant in the response to the Office Action dated September 10, 2008, Richards explicitly states that the first and second heads (315, 316), which the Examiner likens to the first and second securing elements, do *not* rotate to a substantially perpendicular position when deployed.[1]

In Richards, the fastener heads (315, 316) of the fastener (305) "are formed integral with filament 310 so that they *normally extend at a right angle* to the adjoining lengths of the filament," as shown in Figure 10, reproduced below. Richards, col. 6, lines 27-31. (Emphasis added.) During deployment, the fastener heads (315, 316) are each in a first position bent ninety degrees from the normal position illustrated in Figure 10 and delivered into tissue (500, 505) through a sheath (405) of a deployment tool (400), as shown in Figures 11 and 12, reproduced below. *See id.*, col. 4, lines 19-33; col. 7, line 65 to col. 8, line 35. Following deployment through a hole in tissue (500, 505), as shown in Figure 13, reproduced below, "the fastener's heads 315 and 316 will dig into the surrounding tissue as the heads *attempt* to resume their *normal position substantially perpendicular* to the adjoining filament 310." *Id.*, col. 8, lines 53-56 (Emphasis added). However, contrary to the Examiner's assertion, the heads (315, 316) do not move and are not capable of moving to a *second position substantially perpendicular to the first position* but instead only *attempt* to do so and "return only a fraction of the way back to its original perpendicular position." *Id.*, col. 8, line 57 to col. 9, line 5. The heads (315, 316) do not return to their normal, substantially perpendicular position for a variety of reasons identified by Richards, including "the fact that the holes formed in the tissue by the retreating tool 400 are significantly smaller in diameter than the length of fastener heads 315 and 316 (i.e., the distance between angled surfaces 325 and 330 and angled surfaces 326 and 331)" and "the fact that those holes will tend to close inwardly under the pressure of the surrounding resilient tissue." *Id.* Thus, it is clear that the fastener heads (315, 316) are *not* rotatable from a first position to a second position that is substantially perpendicular to the first position when the device is deployed in tissue. Significantly, the fastener heads (315, 316) are not even capable of doing so because their sharply pointed ends engage tissue to hold the heads (315, 316) and the fastener (305) in place as the heads (315, 316) merely *attempt* to move to the normal position.

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[1] In the Office Action the Examiner only relies on the embodiment in Figures 10-14. *See* Office Action, p. 3. Applicant thus focuses on this embodiment although the arguments herein also apply to other embodiments in Richards.

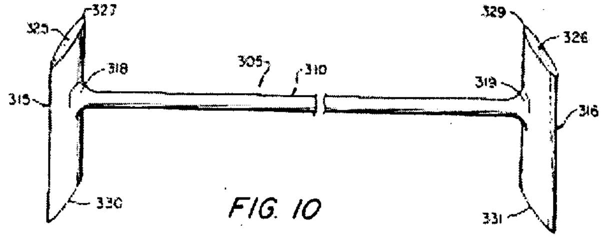

FIG. 10

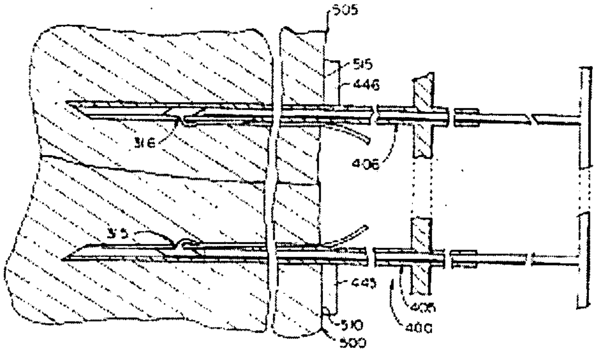

FIG. 12

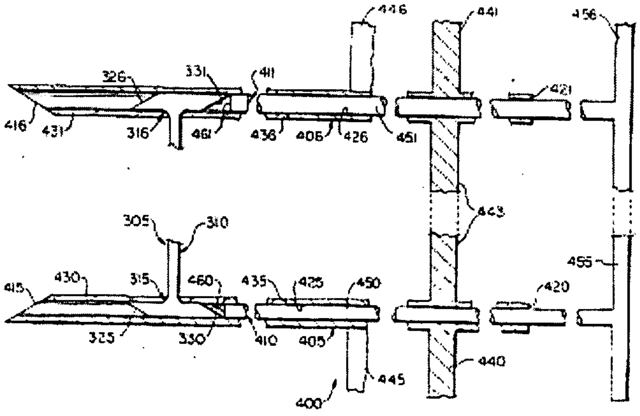

FIG. 11

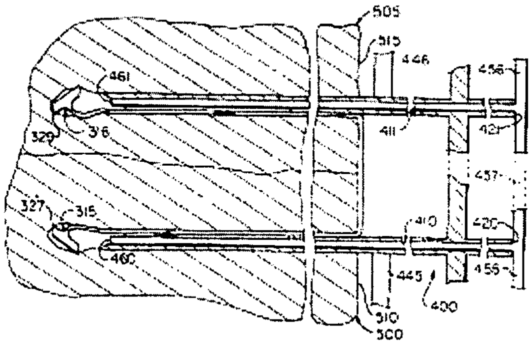

FIG. 13

The fastener (305) including the heads (315, 316) is perfectly effective in securing tissue because "the sharply pointed ends of the fastener's head will nonetheless cause the fastener to penetrate sufficiently into the walls of the tissue so that the fastener will be anchored to the body tissue." *Id.*, col. 5, lines 3-6. Richards specifically identifies these pointed ends of the heads (315, 316) "an important feature of the invention" and that the heads (315, 316) have them so that the heads (315, 316) "will be able to engage the tissue and anchor the fastener in the manner just described." *Id.*, col. 5, lines 7-11. Thus, Richards has other structures that are used to anchor the fastener (305) – a perpendicular orientation of the heads (315, 316) is not only not possible, it is not necessary because Richards relies on other structural features.

It Would Not Have Been Obvious To A Person Skilled In The Art To Modify Richards As Suggested By The Examiner

Despite Richards being very clear that the fastener heads (315, 316) do not rotate back to the normal, substantially perpendicular position when deployed to effectively fasten tissue, the Examiner nevertheless asserts that

> it would be obvious to one having ordinary skill in the art at the time the invention was made, in view of this teaching, to rotate or configure the securing element of Richards et al., so that it is moved or movable from a first position to a second position substantially perpendicular to the first position. Such a modification would ensure firm anchorage of the securing element in tissue, i.e., when the fastener is set deeply in tissue.

Office Action, p. 4.

The Examiner's suggested modification of Richards is improper for at least two reasons.

There Is No Advantage Or Beneficial Result To The Proposed Modification

First, as discussed above, Richards discloses that the heads (315, 316) of the fastener (305) do not rotate to a position substantially perpendicular to their normal position when deployed but that the fastener (305) is perfectly effective to fasten tissue as designed. Indeed, Richards specifically mentions that the sharply pointed ends of the heads (315, 316) are specially designed to effectively secure the fastener (305) in tissue. There is absolutely no reason why a person having ordinary skill in the art would modify Richards as suggested by the Examiner to "ensure firm anchorage of the securing element in tissue" when the heads (315, 316) *already* firmly anchor the fastener (305) to tissue.

The strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. MPEP § 2144(II). Here, there is no advantage to or beneficial result in modifying Richards since the Examiner's own asserted advantage to the modification is exactly what Richards already achieves with its device.

The Examiner's Rejection Improperly Relies On Hindsight Reasoning

Second, the only reason the Examiner has for modifying Richards to rotate or configure the securing element of Richard so that it is moved or movable from a first position to a second position substantially perpendicular to the first position when deployed is a hindsight picking and choosing of features with no rational basis for doing so – a practice expressly forbidden by *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). To make a prima facie showing of obviousness of a claimed invention in light of a given reference, the Examiner should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR*, 127 S. Ct. at 1741. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. *See Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue " and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR*, 127 S. Ct. at 1742.

It is only with the benefit of Appellant's disclosure that the Examiner is able to choose to somehow modify Richards such that the securing element is rotatable from a first position to a second position substantially perpendicular to the first position when deployed. That the Examiner, after having read Appellant's disclosure, can look at Richards and choose to modify the heads (315, 316) does not bar patentability. See *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (stating that the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious") (citations omitted). Indeed, particularly in light of Richards specifically designing the heads (315, 316) *not* to move to a substantially perpendicular position and being perfectly effective for fastening tissue without any modification, it would not have been obvious for one of ordinary skill in the art to modify Richards as suggested by the Examiner.

Accordingly, independent claim 11, as well as claims 12, 13, 15, and 22-26 which depend therefrom, distinguish over Richards and represent allowable subject matter.

Richards in view of McQuilkin

Claims 7-10, 18-21, and 41-44 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Richards in view of U.S. Patent No. 5,219,359 ("McQuilkin"). Applicant respectfully disagrees.

The Examiner relies on Richards to disclose the claimed invention but admits that Richards fails to disclose that at least one through hole formed in the first bioimplantable pledget has a minimum diameter greater than a maximum diameter of the suture. The Examiner also admits that Richards fails to disclose a second bioimplantable pledget having at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The Examiner thus relies on McQuilkin for these features, arguing on pages 5-6 of the Office Action that

> [i]t would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of McQuilkin et al., to include first and second bioimplantable pledgets as claimed with the suture or suture portions and securing elements of Richards et al., and it would have been obvious to modify the diameter of the suture or suture portions of Richards et al., so that the diameters are configured as claimed. Such modifications would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al.

In responding to Applicant's arguments presented in the response to the September 10, 2008 Office Action, the Examiner clarifies that McQuilkin provides

> a teaching regarding the through hole of a pledget, where the through hole has a minimum diameter greater than a maximum diameter of a suture. This teaching was applied to modify the pledget and/or suture of Richards et al. ... Richards et al. indeed teach or suggest [sic] securing elements each having a "proximal end configured for removable attachment

> to an instrument." First, Webster's II New Riverside University Dictionary defines "attach" to include "to fasten or to affix to: connect or join." Then, given the broadest reasonable interpretation of the related term "attachment," indeed, a securing elements of Richards et al. is removably attached, i.e., connected or joined, to tool 100 as seen in figs. 2 and 3. That is, the attachment or connection of the securing element to the tool is brought about by the element's containment within sheath 105, by the element's contact with plunger 110, and by the suture's contact with and bending within slow 130 of the sheath.

Office Action, p. 7-8.

Claims 7-10, 42, and 43

Independent claim 7 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture, a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget. The second pledget has at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element connected to a portion of the suture and being rotatable from a first orientation in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget, to a second orientation in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget. The suture, the first and second pledgets, and the first securing element are effective to fix adjacent layers of living tissue.

As mentioned above, the Examiner admits that Richards fails to disclose a first bioimplantable pledget having at least one through hole formed therein having a minimum diameter greater than a maximum diameter of the suture and that Richards fails to disclose a second bioimplantable pledget having at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The Examiner thus suggests modifying the washer (40B) shown in Figure 8 of Richards, reproduced below, to have a minimum diameter greater than a maximum diameter of the filament (10B) as disclosed in Figures 1 and 13 of McQuilkin, also reproduced below, showing holes (302, 304, 322, 324) in pledgets (30, 32).

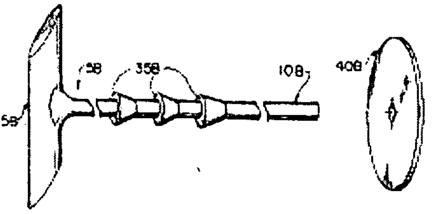

FIG. 8

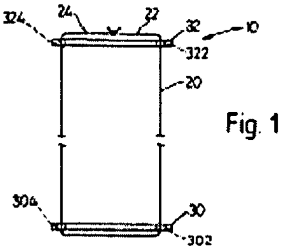

Fig. 1

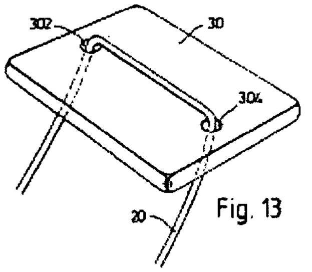

Fig. 13

However, if the hole in the washer (40B) was expanded such that it has a minimum diameter greater than a maximum diameter of the filament (10B) as suggested by the Examiner, the washer (40B) would simply float along the filament (10B) and be unable to secure tissue therewith. The minimum diameter of the hole in the washer (40B) as disclosed in Richards is purposely *less than* the maximum diameter of the fastener's filament (310) because the ribs (35B) that are part of the filament (310) must be larger than the washer's hole so as to secure the fastener (5B) therein. If Richards was modified with McQuilkin as suggested by the Examiner, the fastener (5B) would no longer be operable because the ribs (35B) would either be absent or be too small to hold the washer (40B) in position to secure tissue as shown, for example, in Figure 9 of Richards. Further, adding a second washer (40B) as also suggested by the Examiner would not change the fact that the modified first washer (40B) would be entirely ineffectual without any advantage or beneficial result and therefore would not have been obvious to a person having ordinary skill in the art.

It would also not have been obvious to a person having ordinary skill in the art if, in the alternative, the Examiner is suggesting that the fastener (305) of Figure 10 of Richards, reproduced again below, having two heads (315, 316) be modified to include first and second washers (40B), despite this fastener embodiment not needing washers at all, and for the first washer (40B) and/or the filament (310) to be modified such that the hole in the first washer (40B) have a minimum diameter greater than a maximum diameter of the filament (310). In addition to making the fastener (305) more complicated to use since it is already effective to secure tissue as disclosed by Richards, at least the first washer (40B) if not

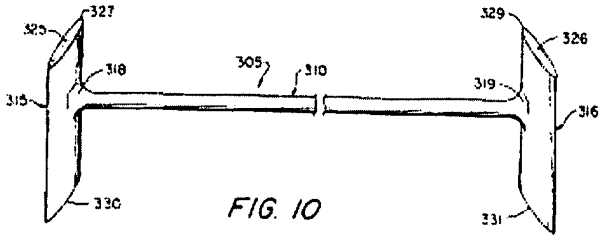

FIG. 10

both washers (40B) would simply be free floating along the filament (310) and serve no purpose.

Accordingly, for at least these reasons, independent claim 7, as well as claims 8-10, 42, and 43 which depend therefrom, distinguish over Richards and McQuilkin, taken alone or in combination, and represent allowable subject matter.

Claims 18-21

As explained above, Richards does not teach or suggest independent claim 11. McQuilkin is relied on for various other features of the claimed invention and does not remedy the deficiencies of Richards. Therefore, claims 18-21, which ultimately depend from claim 11, distinguish over Richards and McQuilkin, either taken alone or together, and represent allowable subject matter.

Claims 41 and 44

Independent claim 41 recites a tissue fixation device including a suture and first and second bioimplantable pledgets. The first pledget has a plurality of through holes formed therein, the suture passing through the through holes. The second pledget has a plurality of through holes formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed. The tissue fixation device also includes a first bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument, and a second bioimplantable securing element being coupled to the suture and having a sharp tip and a proximal end configured for removable attachment to an instrument. The suture, the first and second pledgets, and the first and second securing elements are effective to fix adjacent layers of living tissue.

As mentioned above, the Examiner admits that Richards does not disclose a second bioimplantable pledget or first and second bioimplantable pledgets each having a plurality of through holes formed therein and thus relies on McQuilkin for those features. While Applicant continues to respectfully disagree with the Examiner that Richards discloses a first or second securing element having a proximal end configured for removable attachment to an instrument, the Examiner has not provided any reason why a person having ordinary skill in the art would modify Richards with McQuilkin to have two pledgets each with *a plurality of through holes formed therein*. Such a reason must be provided to establish a prima facie case of obviousness. *See KSR*, 127 S. Ct. at 1741; MPEP § 2143.01.

The only reason provided by the Examiner for any modification of Richards with McQuilkin is that the modification "would allow the device of Richards et al. to be quickly positioned about tissue and to effectively clamp and/or support organ tissue without undue tissue damage, as exemplified in figures 10-12 of McQuilkin et al." Office Action, p. 6. However, as discussed above, the fasteners in Richards *already* achieve this advantage, thereby making any modification of Richards in view of McQuilkin unnecessary and not obvious to a person having ordinary skill in the art.

Moreover, modifying the washer (40B) of Richards as suggested by the Examiner to have a plurality of through holes like the two holes formed in each of the pledgets (30, 32) in McQuilkin would serve no purpose. The pledgets (30, 32) each have two holes to secure the pledgets (30, 32) together so they can fasten tissue. The suture (20) in McQuilkin is threaded through both holes (302, 304) in the bottom pledget (30), then through tissue (50), and then through both holes (322, 324) in the top pledget (32) to secure the pledgets (30, 32) together with the tissue (50) between the pledgets (30, 32). *See* McQuilkin, Figures 3-10; col. 1, line 65 to col. 2, line 12. In contrast, in Richards, a tissue fastener either has a filament extending between a head and a washer (Figure 8) or between two heads (Figure 10) to secure tissue therebetween. There is simply no need for the washer in Richards to be modified to have a plurality of through holes, much less for a *second* washer to be added, as suggested by the Examiner. The fasteners in Richards are perfectly effective for quick positioning about tissue and to clamp and/or support organ tissue without undue tissue damage. Indeed, Richards as disclosed would damage tissue *less* than Richards modified as suggested by the Examiner because Richards only uses a single length of filament inserted through tissue but the proposed modification would require multiple lengths of filament inserted through tissue.

Accordingly, for at least these reasons, independent claim 41, as well as claim 44 which depends therefrom, distinguish over Richards and McQuilkin, taken alone or in combination, and represent allowable subject matter.

Richards in view of Bonutti

Claims 16, 17, 27, and 28 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over

Richards in view of U.S. Patent No. 5,845,645 ("Bonutti"). As explained above, Richards does not teach or suggest independent claim 11. Bonutti is relied on for various dependent claim features and does not remedy the deficiencies of Richards. Therefore, claims 16, 17, 27, and 28, which ultimately depend from claim 11, distinguish over Richards and Bonutti, either taken alone or together, and represent allowable subject matter.

Conclusion

Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

No extension of time is believed to be due with this filing. In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

No fee is believed to be due with this filing. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 100873-283.

Dated: May 8, 2009

Respectfully submitted,

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